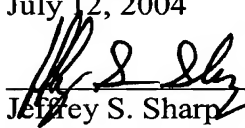


EPW



PATENT
Docket No.: 13024/38629A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of: McMichael, J.)	I hereby certify that this paper and the
)	documents referred to as enclosed
Serial No.: 10/764,161)	herewith are being deposited with the
)	United States Postal Service as First
Filed: January 23, 2004)	Class Mail, postage prepaid, in an
)	envelope addressed to:
For: Method of Treatment of Conditions)	Commissioner for Patents, P.O. Box
by Administration of Streptolysin O)	1450, Alexandria, Virginia 22313-
)	1450, on this date:
Group Art Unit: 1654)	
)	July 12, 2004
Examiner: To be assigned)	
)	Jeffrey S. Sharp
)	Reg. No.: 31,879
)	Attorney for Applicant

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 C.F.R. §§1.56 AND 1.97

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In compliance with 37 C.F.R. §1.97 and the duty of disclosure under 37 C.F.R. §1.56, the attached Form PTO/SB/08A is hereby submitted by the Applicant for consideration in connection with the above-identified patent application. Copies of documents C38-C42 are enclosed herewith. Copies of documents A1-A9, B1-B7 and C1-C37 have been previously submitted to the Patent Office in U.S. Serial No. 10/349,606, from which priority is claimed under 35 U.S.C. §120. However, copies of these documents will be resubmitted at the Examiner's request.

This Information Disclosure Statement is not intended to be an admission that a search has been made, that other relevant art does not exist, or that any of the information disclosed herein constitutes prior art under 35 U.S.C. §102 or §103.

This statement and the Form PTO/SB/08A are submitted before receipt of a first official action on the merits in the above-identified patent application. Accordingly, it is believed that no fee is due in this matter under 37 C.F.R. §1.97(b). However, if it is determined that any appropriate fee is due, please charge Deposit Account Number 13-2855. A duplicate of this paper is enclosed.

Respectfully submitted,

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By: _____

Jeffrey S. Sharp

Registration No.: 31,879

July 12, 2004



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	10/764,161
				Filing Date	January 23, 2004
				First Named Inventor	John McMichael
				Art Unit	1654
				Examiner Name	To be assigned
Sheet	1	of	3	Attorney Docket Number	13024/38629A

U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code ² (if known)		
	A1	5,240,846	08-31-1993	Collins <i>et al.</i>
	A2	5,292,498	03-08-1994	Boucher, Jr.
	A3	5,420,116	05-30-1995	Puchelle <i>et al.</i>
	A4	5,470,838	11-28-1995	von Borstel <i>et al.</i>
	A5	5,576,289	11-19-1996	McMichael, J.
	A6	5,726,160	03-10-1998	McMichael, J.
	A7	5,736,508	04-07-1998	McMichael, J.
	A8	5,948,768	09-07-1999	McMichael, J. <i>et al.</i>
	A9	5,955,442	09-21-1999	McMichael, J.

FOREIGN PATENT DOCUMENTS				
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Country
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)		
	B1	WO 92/11016	07/09/92	WIPO
	B2	WO 93/12240	06/24/93	WIPO
	B3	WO 94/23048	10/13/94	WIPO
	B4	WO 95/25800	09/28/95	WIPO
	B5	WO 96/32138	10/17/96	WIPO
	B6	WO 96/40059	12/19/96	WIPO
	B7	WO 97/05195	02/13/97	WIPO

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Alton, E.W.F.W. <i>et al.</i> , "Noninvasive liposome-mediated gene delivery can correct the ion transport defect in cystic fibrosis mutant mice," <i>Chemical Abstracts</i> , 119:62 (1993) (ABSTRACT 217089w)	
	C2	Badesch <i>et al.</i> , "Continuous Intravenous Epoprostenol for Pulmonary Hypertension Due to the Scleroderma Spectrum of Disease, A Randomized, Controlled Trial," <i>Ann. Intern. Med.</i> , 132:425-434 (2000).	
	C3	Baker, R.C., "Pitfalls in Diagnosing Acute Otitis Media," <i>Pediatric Annals</i> , 20:591-593, 596-598 (1991).	
	C4	Barst <i>et al.</i> , "A Comparison of Continuous Intravenous Epoprostenol (Prostacyclin) With Conventional Therapy for Primary Pulmonary Hypertension," <i>N. Eng. J. Med.</i> , 334:296-301 (1996).	

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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			Group Art Unit	1654	
			Examiner Name	To be assigned	
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C5	Berkow, R. (Ed.), The Merck Manual of Diagnosis and Therapy, Sixteenth Edition, Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, N.J. pp. 600-602 (1992).
C6	Berman, S., "Otitis Media in Developing Countries," <i>Pediatrics</i> , 96:126-131(1995).
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C8	Carman <i>et al.</i> , "A Primary Care Approach to the Patient with Claudication," <i>Am. Fam. Physician</i> , 61:1027-1032 (2000).
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C13	Flotte, T.R., <i>et al.</i> , "Stable <i>in vivo</i> expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associated virus vector," <i>Chemical Abstracts</i> , 120:229(1994) (ABSTRACT 46918e)
C14	Furth <i>et al.</i> , "Gene Transfer into Somatic Tissues by Jet Injection," <i>Analytical Biochemistry</i> , 205:365-368 (1992).
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C17	Goldhaber <i>et al.</i> , "Low-Dose and Subsequent Peripheral Arterial Surgery in the Physicians' Health Study," <i>Lancet</i> , 340:143-145 (1992).
C18	Harrison <i>et al.</i> , "Structural Features of Interstitial Lung Disease in Systemic Sclerosis," <i>Am. Rev. Respir. Dis.</i> , 144:706-713 (1991).
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C22	Karver, S.B., "Otitis Media," <i>Ear, Nose and Throat Disorders</i> , 25:619-632(1998).
C23	Klein, J.O., "Otitis Media," <i>Clinical Infectious Disease</i> , 19:823-833 (1994).
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C26	Marshall, E., "Gene Therapy's Growing Pains," <i>Science</i> , 269: 1050-1055 (1995).

Examiner Signature		Date Considered	
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			Group Art Unit	1654	
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Sheet	3	of	3	Attorney Docket Number	13024/38629A

	C27	Patterson et al., "Value of a Supervised Exercise Program for the Therapy of Arterial Claudication," <i>J. Vasc. Surg.</i> , 25:312-319 (1997).	
	C28	Razin et al., "Protein Kinases C- β and C- ϵ Link the Mast Cell High-Affinity Receptor for IgE to the Expression of c-fos and c-jun," <i>Proc. Natl. Acad. Sci. (USA)</i> , 91:7722-7726 (1994).	
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	C30	Rosenfeld, J. et al., "Acute Otitis Media in Children," <i>Primary Care; Clinics in Office Practice</i> , 23(4):677-686(1996).	
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	C33	Silver et al., "Evaluation and Management of Scleroderma Lung Disease Using Bronchoalveolar Lavage," <i>Am. J. Med.</i> , 88:470-476 (1990).	
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	C35	Visa et al., "The Value of Fasciectomy in the Surgical Approach of the Dupuytren's Disease," <i>Romanian Journal of Hand and Reconstructive Microsurgery</i> , 5:9-13 (2000).	
	C36	Wallaert et al., "Subclinical Pulmonary Involvement in Collagen-Vascular Diseases Assessed by Bronchialveolar Lavage," <i>Am. Rev. Respir. Dis.</i> , 133:574-580 (1986).	
	C37	White et al., "Cyclophosphamide is Associated with Pulmonary Function and Survival Benefit in Patients with Scleroderma and Alveolitis," <i>Ann. Intern. Med.</i> , 132:947-954 (2000).	
	C38	Siebold et al., "Recombinant Human Relaxin in the Treatment of Scleroderma, A Randomized, Double-Blind, Placebo-Controlled Trial," <i>Ann. Intern. Med.</i> , 132:871-879 (2000).	
	C39	Murinda et al., "Isolation of Mastitis and Food-Borne Pathogens in Bulk Tank Milk and Fecal Samples from Cull Dairy Cows," Schrick et al., <u>Department of Animal Science Annual Report</u> , The University of Tennessee, Knoxville, in press.	
	C40	Taranta et al., "The Relationship of Sydenham's Chorea to Infection with Group A Streptococci," <i>Am. J. Med.</i> , 20:170-175 (1956).	
	C41	Kiessling et al., "Antineuronal Antibodies in Movement Disorders," <i>Pediatrics</i> , 92:39-43 (1993).	
	C42	Askanas et al., "A New Program for Investigating Adult Human Skeletal Muscle Grown Aneurally in Tissue Culture," <i>Neurology</i> , 25:58-67 (1975).	

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